IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ALL PLAINTIFFS LISTED IN EXHIBIT "A"	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF CHRISTINA PRAMUDJI, M.D.

Plaintiffs respectfully request that this Court preclude defense expert Christina Pramudji, M.D., a urologist with a subspecialty in pelvic floor medicine, from giving opinions on: (1) the adequacy of Defendants' product warnings and IFUs; (2) whether Defendants' transvaginal mesh products are defectively designed; (3) the safety and efficacy of Defendants' products based on her own practice; and (4) whether or not the polypropylene mesh in the mesh products degrades beyond what she has personally observed in her own practice.

LEGAL STANDARD

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. On the issue of qualifications, "the district court must decide whether the expert has 'sufficient specialized knowledge to assist the jurors in deciding the particular issues in the case.'" *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999)).

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents "scientific knowledge," meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury—i.e., whether it is relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). The relevance aspect of the inquiry is often discussed in terms of whether the expert's opinions "fit" the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

To meet the standard of reliability, the testimony "must be supported by appropriate validation—i.e., 'good grounds,' based on what is known. In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1383 (4th Cir. 1995).

There are five factors courts often consider, taken from the *Daubert* opinion, in assessing the reliability of expert testimony:

- (1) whether the testimony has been tested,
- (2) whether it has been published or exposed to peer review,
- (3) its rate of error,
- (4) whether there are standards and controls over its implementation, and
- (5) whether it is generally accepted.

See Cavallo v. Star Enterprise, 100 F.3d 1150, 1158 (4th Cir. 1996). However, "the factors discussed in *Daubert* were neither definitive, nor exhaustive." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

Courts should focus on expert witnesses' "principles and methodology, not on the conclusions that they generate." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). This is because "*Daubert* governs whether evidence is admitted, not how persuasive it must be to the factfinder." *Cavallo*, 100 F.3d at 1158. Finally, the proponent of the testimony has the burden of proving both relevance and reliability. *Bickel v. Pfizer, Inc.*, 431 F. Supp. 2d, 918, 921 (N.D. Ind. 2006).

FACTUAL BACGROUND

Dr. Pramudji has issued two reports in this litigation, addressing five different Ethicon products. One report addresses the TVT-R and TVT-O (the "TVT Report"),[1] and the second report addresses the Prolift, Prosima, and Gynemesh PS products (the "Prolift Report").[2] (Collectively, the "subject products"). These reports contain the same general opinions applicable to all five products:

- The risks are adequately described in the IFU and professional education materials. (TVT Report, Ex. B, at 5; Prolift Report, Ex. C, at 6).
- Defendants' products at issue are not defective in their design and have a positive benefit to risk profile. (TVT Report, Ex. B, at 5; Prolift Report, Ex. C, at 4, 6).
- The data in women does not support that the Prolene mesh degrades, or that if it did, it would have a clinically significant effect. (TVT Report, Ex. B, at 2; Prolift Report, Ex. C, at 3).

[1] Expert Report of Christina Pramudji, M.D., (TVT & TVT-O), attached as Exhibit B.
[2] Expert Report of Christina Pramudji, M.D., (Gynemsh PS, Prolift, and Prosima) attached as Exhibit C.

Dr. Pramudji also intends to offer opinions about her personal success rates with the subject products, specifically that the products are very successful with a high patent satisfaction and few complications. (Pramudji Deposition, March 24, 2016, portions attached as Exhibit D, at 236:18-20).

ARGUMENT

1. DR. PRUMADJI'S OPINIONS ON THE ADEQUACY OF DEFENDANTS' WARNINGS SHOULD BE PRECLUDED PURSUANT TO *DAUBERT*.

Dr. Christina Pramudji's testimony is unreliable, as she admits her opinions on the adequacy of Defendants' warnings are based on nothing more than personal conviction. Thus, they are *ipxe dixit* opinions and precluded under *Daubert*. Dr. Pramudji admits she has no knowledge of FDA requirements and no knowledge of industry standards. She admits she performed no research on standards of any kind before publishing her expert report. Finally, she admits that her opinions are based solely on her subjective beliefs and her status as an "expert." Such testimony lies at the heart of what *Daubert* and its progeny have found inadmissible.

Dr. Pramudji admits she did not rely on any standards when forming her opinions regarding the sufficiency of Defendants' warnings—including FDA regulations and Defendant's own protocol—and that her opinions are not grounded in any objective standard.[3] Dr. Pramudji simply provides her own *ipse dixit* to support her opinions.

> Q. You could not give me an objective standard that you applied….It's simply what you think is right or adequate based on your own experience, right?
>
> [Def. counsel]: Form.
>
> A. Yeah. I would say that's correct.[4]

[3] Pramudji Deposition, Sept. 17, 2014, portions attached as Exhibit E, at 64:16-65:8.
[4] *Id.* at 65:10-16.

Dr. Pramudji is not a regulatory expert.[5] She is not an expert on FDA regulations or device warnings.[6] In fact, she has no familiarity at all with such regulations.[7] For example, she does not know what the FDA regulations require in the IFU or patient brochure for Defendants' products.[8] She is likewise unfamiliar with defendants' own internal standards for determining the contents of warnings.[9] Thus, she certainly did not rely on defendants' internal guidelines in forming her opinions on warnings.[10] She has no knowledge of any requirements defendant had to meet before marketing their products.[11]

Dr. Pramudji also has no knowledge of—and has conducted no research into—what risk information Defendants possessed at the time they began marketing the products at issue.[12] By definition, then, she cannot identify which risks should have been included in the IFU or whether Defendants warned of all known risks. Similarly, Dr. Pramudji had no knowledge of the additional risks and complications (or their increased occurrence, duration, or severity) that Defendants learned about after the products were on the market; and therefore, Dr. Pramudji has no knowledge of the risks that should have been included in subsequent IFUs.[13]

Dr. Pramudji made no attempt to determine whether Defendants' protocol required them to warn of substantial risks.[14] In reaching her conclusions, she did not consider how Defendants responded to risk information.[15] Dr. Pramudji made no attempt to learn, for instance, that Defendants' executives have repeatedly acknowledged that the IFU must warn of all significant

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5 *Id*. at 16:3-5,
6 *Id.* at 16:6-13
7 *Id.* 16:25-17:5
8 *Id.* at 78:19-79:2
9 *Id.* at 17:6-11
10 *Id.* at 17:12-19
11 *Id.* at 17:20-23.
12 *Id.* at 17:24-18:7; *see also, Id*. at19:11-21.
13 *Id.* at 18:22-19:10
14 *Id.* at 65:23-66:6
15 *Id.* at 20:6-9

risks. For instance, Dr. Charlotte Owens, Ethicon's worldwide medical director in March 2005—when Prolift was first introduced—testified that the IFU must clearly and unambiguously communicate all contraindications, warnings, precautions, and adverse events to physicians.[16] Dr. David Robinson, the director after Owens left, testified that physicians rely on the IFU, hence any substantial risk must appear there.[17] Sean O'Bryan of the Regulatory Affairs Division testified that both company policy and FDA regulations mandate that all warnings of substantial risks appear in the IFU.[18] It is clear that Dr. Pramudji ignored these standards because, had she read them, she would have been compelled to admit the standards were violated. So, instead, she relies on an illusory, subjective standard that cannot be challenged or tested.

Dr. Pramudji's opinion on the adequacy of Defendants' warnings should be excluded because it is based on no objective criteria. Federal courts have consistently held that *ipse dixit* opinions – those justified solely by the fact that the expert holds them – are inadmissible. *See, e.g.*, *GE v. Joiner*, 522 U.S. 136, 146 (1997); *see also Pampered Chef v. Alexanian*, 804 F. Supp. 2d 765, 794 (N.D. Ill. 2011) ("If admissibility could be established merely by the *ipse dixit* of an admittedly qualified expert, the reliability prong would be, for all practical purposes, subsumed by the qualification prong."). The Fourth Circuit concurs. *Holesapple v. Barrett*, 5 Fed. Appx. 177, 2001 WL 208490 at *2 ("[I]t still is a requirement that the expert opinion evidence be connected to existing data by something more than the 'it is so because I say it is so' of the expert.").

This Court has also excluded *ipse dixit* opinions. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 603 (S.D.W. Va. 2013) (excluding testimony where expert's "opinions are simply *ipse dixit*

[16] Dr. Owens Deposition, portions attached as Exhibit F, at 259:5-9; 260:12-261:6; 262:7-13; 309:23-310:3.
[17] Dr. Robinson Deposition, portions attached as Exhibit G, at 488:11-18, 489:4-10; 492:23-493:8; 458:18-459:2, 459:12-19.
[18] O'Bryan Deposition, portions attached as Exhibit H, at 107:3-21; 327:22-328:7.

opinions"). *See also In re Digitek Prods. Liab. Litig.*, 821 F. Supp. 2d 822, 840 (S.D.W. Va. 2011) (Goodwin, J.) ("Dr. Mason's reason for using the long-delayed draw in his analysis is this: '[I]t's what I've got. And that's the way I'm doing it.' That is ***ipse dixit*** condemned by *Daubert* and its progeny."); *Hines v. Wyeth*, Civ. Act. No. 2:04-0690, 2011 WL 2680814, at *6 (S.D.W. Va. July 8, 2011) (Copenhaver, J.) (excluding expert testimony because of the analytical gap between the data and opinions derived).

To be admissible, expert testimony must explain the link between the available evidence or data and the expert's opinion. *United States v. Mamah*, 332 F.3d 475, 478 (7th Cir. 2001); *see also Cunningham v. Masterwear, Inc.*, No. 1:04-cv-1616-JDT-WTL, 2007 WL 1164832, at *9 (S.D. Ind. Apr. 19, 2007) ("It is not enough for an expert to say this is my data and that is my conclusion without connecting the two."); *Mid-State Fertilizer Co. v. Exchange Nat. Bank of Chicago*, 877 F.2d 1333, 1390 (7th Cir. 1989) ("An opinion has a significance proportioned to the sources that sustain it.").

Clearly, then, an expert's credentials alone cannot establish the admissibility of an opinion. *Minasian v. Standard Chartered Bank, PLC*, 109 F.3d 1212, 1216 (7th Cir. 1997) ("Judges [must] not be deceived by the assertions of experts who offer credentials rather than analysis."). Nor can the experience of the expert justify an opinion, by itself, without an explanation of how that experience leads to the conclusion reached. *See* Fed. R. Evid. 702 adv. com. note ("If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts.")

Rather, opinions must be based on objective standards. *See Superior Aluminum Alloys, LLC. v. U.S. Fire Ins. Co.*, No. 1:05-CV-207, 2007 WL 1850858, at *6 (N.D. Ind. June 25, 2007)

(excluding expert testimony not based on any objective standard); *N. Star Mut. Ins. Co. v. Zurich Ins. Co.*, 269 F. Supp. 2d 1140, 1148 (D. Minn. 2003) (excluding testimony because expert did "not cite any treatise, any industry code of conduct, or anything outside of his self-professed opinion, to demonstrate that the opinion has any legitimacy.").[19]

In *Superior Aluminum Alloys*, the court recognized that "a court's reliability analysis does not end with its conclusion that an expert is qualified to testify about a given matter." *Superior Aluminum Alloys*, 2007 WL 1859858, at *5. In rejecting the expert's testimony, the court wrote:

> By baldly invoking "my expertise" with no explanation of how this expertise led him to reach his opinions, Deimling fails to provide the Court with any means to assess the reliability of his opinions.
>
> ***
>
> Deimling provides no explanatory link between the facts that he reviewed and his opinions, making them inadmissible "bottom lines."

Id. at *7.

Similarly, in this case, by Dr. Pramudji's own admission, she has no idea what is required by any standard. She did no research or analysis on the subject. In fact, she did not even attempt to discover what defendant's own internal standards were. Dr. Pramudji admitted that her opinions are based on nothing more than her subjective views. Those opinions are inadmissible under the *Daubert* line of cases.

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[19] *See also Grdinich v. Bradlees*, 187 F.R.D. 77, 81-82 (S.D.N.Y. 1999) ("Without industry standards to rely upon, [the expert] seems to base his conclusion on his own authority."); *Navarro v. Fuji Heavy Indus., Ltd.*, 925 F. Supp. 1323, 1329 (N.D. Ill. 1996) ("[The expert] refers to no specific applicable standard."), *aff'd*, 117 F.3d 1027 (7th Cir. 1997); FED. R. EVID. 702 (expert testimony is unreliable unless "the expert's theory can be challenged in some objective sense" and is not "simply a subjective, conclusory approach that cannot reasonably be assessed for reliability.").

II. Dr. Pramudji should be precluded from giving opinions on the design of the mesh products.

Dr. Pramudji should be precluded from offering opinions regarding the design of the subject products. Specifically, she should be precluded from offering any opinions regarding: (1) whether or not the subject products are defectively designed; or (2) the sufficiency of the Defendants' risk assessments performed during the design of the products—the design failure modes effects analysis (dFMEA), the process failure modes effects analysis (pFMEA), and the application failure modes effects analysis (aFMEA).

Dr. Pramudji should be precluded from opining about the design of the subject products because she admits that she is not an expert on design, beyond her personal evaluation of how a device feels in her hands:

> Q. (By Mr. Faes) Am I correct that I would not expect you to offer opinions on the design of the Prosima?
>
> MR. GAGE: Object to form.
>
> THE WITNESS: My opinions would go to how I feel the design is based on use in my hands and based on patient results. So I feel very confident and familiar with evaluating the design based on those parameters.[20]
>
> Q. Have you ever worked on the design team for a medical device?
>
> A. THE WITNESS: No, Only on a consulting basis.
>
> Q. Am I correct in that you're not a biomedical engineer?
>
> A. I'm not a biomedical engineer. I've studied it, but I'm not a biomedical engineer.[21]

This Court has previously recognized the importance of an expert's admission that he is not an expert. In the *Bard* litigation, this Court precluded Dr. Shull from giving warnings opinions because he had testified that "I would not claim to be an expert in that area." *In re C.R.*

[20] Pramudji March 24, 2016 Dep., Ex. D, at 186:14-186:18.
[21] *Id.* at 186:14 – 186:18

Bard, Inc., 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013), *amended on reconsideration in part* (June 14, 2013). That same analysis applies here to Dr. Pramudji, who admitted she is not an expert on design beyond how the subject devices perform in her hands. As such, she should be precluded from giving any opinions related to design of the subject products.

a. Dr. Pramudji did not review Defendants' key documents related to product design, and even if she had reviewed them, Dr. Pramudji has no base of knowledge as to what those documents would demonstrate.

Dr. Pramudji should also be precluded from opining about the design of the subject products because she has not reviewed Defendants' internal documents about the design process. This issue was central to the exclusion of design opinions by a urogynecologist for the plaintiffs in the Boston Scientific litigation. *See Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *14 (S.D. W. Va. Apr. 24, 2015) (excluding Dr. Shull in part because he "reached opinions on the improper design of the Uphold without having first considered BSC's design protocols"). This Court reasoned that "regardless of the literature he has reviewed or the experience he has gained, a necessary piece of data remains missing from Dr. Shull's methodology. Without any reliable, demonstrated knowledge of BSC's internal design procedures, Dr. Shull cannot substantiate his opinion that these procedures were (1) departures from the norm; (2) not followed by BSC; or (3) lacking in any way." *Id.*

Dr. Pramudji also confirmed she has not read the failure modes and effects analysis for the subject products, and does not know what that phrase means.[22] As Ms. Owens discussed, the purpose of a design failure modes and effects analysis ("dFMEA") is to "review the potential risk associated with the design of the product."[23]

[22] Pramudji March 24, 2016 Dep., Ex. D, at 186:23 – 187:2, 187:15 – 188:7).
[23] Owens Dep., Ex. F, at 485:14-24. Ms. Owens's cited deposition related to the Prolift product only, but the discussion quoted was not product-specific.

> Q. And when you say "associated with the design of the product," that means that when the product is in a woman's body and the product was manufactured completely consistent with the specifications, these are the things that could go wrong and harm a patient, correct?
>
> A. Correct.[24]
>
> ***
>
> Q. And you understood that it was required that you capture all of the different failure modes, all the things that could go wrong in the procedure, even if the doctor was properly trained and following the proper procedure, and the effects of those failure modes, the hazards that could occur, and the resulting harms, and you were supposed to capture all of them, correct?
>
> A. Yes, all that we could conceive of, yes.[25]

The same analysis applies to Dr. Pramudji in this case. Dr. Pramudji should have reviewed these documents in forming her opinions about the design of the subject products; but not only did she fail to review those documents, she did not know what the phrase "failure modes and effects analysis" means.

> Q. (By Mr. Faes) Do you know what a design failure modes analysis is?
>
> A. I don't—I'm not familiar with that term.[26]
>
> ***
>
> Q. Do you know what a process failure modes analysis is?
>
> A. I'm not sure.
>
> Q. Do you recall if you've reviewed any process failure modes effects analysis with the Prosima, Prolift, or Gynemesh PS devices?
>
> A. I'm not sure.
>
> Q. Do you know what an application failure modes effects analysis is?
>
> A. I'm not sure.

[24] *Id.* at 485:25-486:7
[25] *Id.* at 449:12-22.
[26] Pramudji March 24 Dep., Ex. D, at 186:23 – 187:2.

> Q. Do you recall if you've ever reviewed any of those for the Gynemesh PS, Prolift, or Prosima device
>
> A. I'm not sure.[27]

Because she did not review the relevant design documents, and does not even know that the failure modes effects analyses are or what they represent, Dr. Pramudji lacks the required knowledge to give a reliable opinion about the design of Defendants' transvaginal mesh products. Based on the foregoing, Dr. Pramudji's opinions on the issue of product design should be excluded.

III. Dr. Pramudji's statements about her personal experience related to the safety and efficacy of the subject products should be excluded because it is not based on any objective standard, and her analysis and methodology are flawed

Dr. Pramudji should be precluded from testifying about her perceived safety, efficacy, and patient satisfactions rates with the subject products from her practice, as that information is Dr. Pramudji's own *ipse dixit*, cannot be tested or confirmed, and is entirely unsupported by any reliable methodology, statistical information, or analysis. As an example, Dr. Pramudji's deposition includes the following testimony:

> Q. Doctor, are you going to offer – do you plan to offer an opinion in this case about your personal success rate with the Prosima, Prolift, or Gynemesh PS products?
>
> A. Yes
>
> Q. What is the opinion that you intend to offer about your personal success rate with those products?
>
> A. What I found is that the products were very successful with a high patent satisfaction with few complications.
>
> Q. Do you intend to offer a numeric success rate –

[27] *Id.* at 187:15 – 188:7.

A. No, I don't have a –

Q. in conjunction with those products?

A. No, I don't have a calculated numeric rate for my patients

Q. Same question with regard to complication or erosion or extrusion rates, do you intend to offer an opinion in this case with regard to a numeric percentage of complications or extrusion rates that you've experienced personally?

A. Perhaps, I have in the past calculated reoperation rates, but I can't recall right now if that was on Prolift or on TVT. I would have to go back and look at my operative logs.

Q. So—

A. So I may have that rate on—

Q. Just reoperation rates?

Q. Not exposure or extrusion rates?

A. Correct.[28]

Defendants' experts have backed off of giving opinions about numerical complication rates, perhaps recognizing that they are inappropriate, unsupported and inadmissible, so Dr. Pramudji now seeks to backdoor essentially the same opinion by substituting an imprecise, undisclosed re-operation rate in its place. This should not be permitted, as Dr. Pramudji lacks any reliable methodology or analysis to support her conclusions:

Q. Can you tell me how you arrived at those reoperation rates?

A. I took my total number of reoperations and my total number of cases and just divided it.

Q. And what--

A. So it's a rough number.

Q. And what is the numerator and denominator for those?

[28] Pramudji March 24, 2016 Dep., Ex. D, at 236:9 – 237:22.

A. I don't recall, as I sit here right now. I would have to look at it.[29]

***

Q. Did you do any kind of analysis of patients that were lost to follow-up?

A. No, I did not.[30]

***

Q. But you can't state a specific year that you started and stopped?

A. No, I can't remember right now.[31]

***

Q. So your reoperation rates that you calculated would exclude any patients that went to other doctors for reoperation that you didn't know about, correct?

A. Yes. But kind of what I did in reverse, which this is very rough, but I included patients that came in from other doctors in my reoperation rate. So some patients were not my original -- it's a very rough analysis. There's just sort of, okay, I did this many implants; how many reoperations did I do? And this is just -- this isn't even -\- this is just like a mesh exposure, mesh explant type reoperation. It's not comprehensive .[32]

Dr. Pramudji's own testimony indicates that the only numerical rate she may be able to express is a re-operation rate, and by her own admission, it is a very rough analysis. Dr. Pramudji is asserting and relying on alleged safety, efficacy, and patient satisfaction data from her own practice, and yet she has no foundation whatsoever for that assertion. She only tracks re-operation rates, but even for that metric she does not track the time frame, mesh product removed, or even whether the product was implanted by her or another physician. As such, plaintiffs have no reasonable way of testing the veracity of Dr. Pramudji's claims. Because there is no foundation for this testimony, Dr. Pramudji should be prohibited from providing this

[29] Pramudji March 24, 2016 Dep., Ex. D, at 237:23 – 238:9.
[30] *Id.* at 239:5-7.
[31] *Id.* at 239:17-19.
[32] *Id.* at 240:13-241:4.

testimony. Allowing her to do so would be akin to permitting an improper opinion about her personal numerical complication rates.

IV. Dr. Pramudji's opinions on mesh degradation should be limited to what she has observed in her clinical practice.

Dr. Pramudji has stated the opinion in her expert reports that "the data in women does not support that the Prolene mesh degrades, or that if it did, it would have a clinically significant effect."[33] Dr. Pramudji simply does not have the requisite experience to proffer this opinion, nor has she utilized *any* method—let alone a reliable method—to reach these conclusions. Dr. Pramudji's opinions amount to nothing more than baseless assumptions, and the law is clear that such "unsupported speculation" is not only insufficient, but precisely what *Daubert* aims to prevent. [34] This court previously allowed Dr. Pramudji's to testify whether she has observed degradation in her clinical practice,[35] but her current opinions go beyond what Dr. Pramudji has seen in her clinical practice, and go beyond her qualifications.

Dr. Pramudji does not have any specialized education or training specifically related to polypropylene or the scientific, chemical or structural make-up of Ethicon's medical devices or any of their components, including polypropylene mesh. Dr. Pramudji does claim to be qualified as an expert in these subjects, but instead concedes that she ". . . had some training in polymers and chemistry. But, you know, [] that was a long time ago."[36] Illustrating her own lack of knowledge, Dr. Pramudji readily admits that she does not know about the scientific properties of the polypropylene mesh used in the Ethicon TVT-O. She clearly states that she does not know

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[33] TVT Report, Ex. B, at 2; Prolift Report, Ex. C, at 3.
[34] *Brown v. Auto-Owners Ins. Co.*, No. 96-2613, 1997 U.S. App. LEXIS 23559, *3(4th Cir., Sept. 8, 1997)(the expert's testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation); *see also Bryte v. Am. Household, Inc.*, 429 F.3d 469, 477 (4th Cir. 2005).
[35] *Huskey v. Ethicon* 29 F. Supp. 3d 691, 726-27 (S.D West Virginia 2014).
[36] Pramudji Deposition, April 11, 2014, portions attached as Exhibit I.

whether or not there are any additives to the polypropylene, whether or not it is oxidized before implantation, or what its molecular weight is.[37] She also does not know the chemical processes involved with degradation:

> Q. … you know that it's made of polypropylene, but you're not intending to offer opinions here concerning the chemical processes that are involved with polypropylene?
>
> A . I don't know about the chemical process.[38]

Moreover, Dr. Pramudji concedes she has never done any of the following:

- Tested polypropylene mesh to see if it degrades;
- Looked at polypropylene under a microscope;
- Looked at explanted polypropylene sutures and analyzed them for degradation;
- Asked a pathologist about polypropylene degradation;
- Sought out and/or reviewed any additional information from Ethicon regarding the chemical makeup of polypropylene mesh;
- Performed independent studies related to polypropylene degradation.[39]

When asked directly how, in fact, she knows whether or not polypropylene mesh deteriorates, Dr. Pramudji testified: "Because it doesn't."[40] Dr. Pramudji attempts to support her opinions by stating that she has not heard of degradation in her review of literature.[41] However, Dr. Pramudji confirms that she reviewed literature and documents provided by Ethicon, but did not ask Ethicon to provide her with all of the information that they have concerning degradation.[42] Though it does not appear that Dr. Pramudji has performed any specific research or sought out any information directly on this topic, she concedes that she has seen what she

[37] *Id*. at 133:19-134:2
[38] *Id.* at 134:7-13.
[39] *Id*. at 132:1-134:10
[40] *Id*. at 134:16-134:19
[41] *Id.* at 136:21-138:15
[42] *Id.* at 132:6-11

considers "remote studies" that do, in fact, report polypropylene degradation.[43] Under *Daubert*, a literature review must be performed appropriately in order to be part of a reliable methodology; as part of this, the Court must find more than an expert's own "hypothesis and speculation."[44] Most concerning is Dr. Pramudji's assertion that there is *nothing* she could learn about the material used in the Ethicon TVT or TVT-O products, or that she could see in the medical literature about polypropylene degradation, that would change her opinion.[45]

Reviewing selective literature provided by Defendants that does not address degradation, and presumptively disregarding any literature contrary to her opinion, is not a foundation for "expert" testimony that degradation does not occur. Dr. Pramudji has admittedly not used any scientific or medical methodology to come to her conclusions, and expert speculation such as this should be excluded.

CONCLUSION

Based on the foregoing, Dr. Pramudji should be precluded from giving opinions on: (1) the adequacy of Defendants' product warnings and IFUs; (2) whether Defendants' transvaginal mesh products are defectively designed; (3) the safety and efficacy of Defendants' products based on her own practice; and (4) whether or not the polypropylene mesh in the mesh products degrades beyond what she has personally observed in her own practice.

[43] *Id.* at 136:21-138:15
[44] *Doe v. Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 2d 465, 473-74 (M.D.N.C. 2006) (excluding expert testimony based on a literature review, stating that it must be based on more than "hypothesis and speculation," that the review was "disconnected" and not derived by the scientific method.)
[45] Dr. Pramudji Dep. Tr., 04-11-2014; 141:7-142:3; Plaintiff's Motion, Exhibit 8

Dated: April 21, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on April 21, 2016, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

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Attorney for Plaintiffs